DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 15, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-90

David F. Kinsey, Partner
Sweetwater Farms
1615 Columbia Park Trail
Richland, Washington 98352

WARNING LETTER

Dear Mr. Kinsey:

We inspected your firm located at 1615 Columbia Park Trail, Richland, Washington, on July 24, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. A FDA 483 form (copy enclosed) listing the deviation was presented to you at the conclusion of the inspection on July 24, 2000. This deviation causes your sprouts to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act through links in FDA's homepage at www.fda.gov.

Your firm's sprouts are adulterated within the meaning of 402(a)(4) of the Act because they are prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm. In addition, cross connections and dead legs were observed with the plumbing for the alfalfa soak tanks, the chlorinator for the spray water holding tanks is not maintained, specifically, the filter was noted to be completely encrusted and the chlorinator was not working, mold was observed on shelves and walls in the alfalfa grow room, there is no pest control program in place, and product is packed and held under unshielded fluorescent lights.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Althar, Compliance Officer at (425) 483-4940 or via e-mail at lalthar@ora.fda.gov.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483 –7/24/00
21 CFR PART 110
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement